510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k031565

B. Analyte:
Influenza A/B nucleoprotein antigens

C. Type of Test:
Rapid Immunochromatographic test

D. Applicant:
Remel, Inc.

E. Proprietary and Established Names:
Xpect™ Influenza A/B

F. Regulatory Information:

1. Regulation section:
21 CFR 866.3330; Influenza virus serological reagents

2. Classification:
Class I
3. Product Code:
GNX; Antigens, CF, Influenza Virus A, B, C.
4. Panel:
Microbiology (83)

G. Intended Use:

1. Intended use(s):
REMEL's Xpect™ Influenza A/B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture
2. Indication(s) for use:
REMEL's Xpect™ Flu A/B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.
3. Special condition for use statement(s):

4. Special instrument Requirements:

H. Device Description:

The Xpect™ Influenza A/B is a chromatographic immunoassay for the qualitative detection of influenza A and influenza B viral antigens. The test device

incorporates separate membrane strips for influenza A and for influenza B. To perform the test, the patient specimen is diluted and added to the sample well of the device. The mixture moves along the membranes by capillary action. If present, influenza A or B viral antigens in the patient sample bind anti-influenza A or B conjugated antibodies. A visible line forms as a complex of antibody-antigen-antibody coated colored particles is captured in the test region (T). Antibody coated colored particles not bound at the test line are later captured in the control region (C) containing goat anti-mouse antibody. A visible line will always appear in the control region indicating that the test is working properly. The presence of a control line combined with the absence of a visible test line is interpreted as a negative test result.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   BD Directigen Flu A+B
2. Predicate K number(s):
   k001364
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Procedure	Qualitative; Influenza A and B viral antigens with differentiation.	Qualitative; Influenza A and B viral antigens with differentiation.
Differences		
Item	**Device**	**Predicate**
Assay	Enzyme Immunoassay (EIA) membrane assay	Enzyme Immunoassay (EIA) membrane assay
Specimen Type	Nasal wash, nasal swab, and throat swab specimens	Nasopharyngeal wash, nasopharyngeal aspirate, nasopharyngeal swab, lower nasal swab, throat swab and bronchoalveolar lavage specimens

J. Standard/Guidance Document Referenced (if applicable):

K. Test Principle:

Immunochromatographic Test

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   Reproducibility testing was conducted at four sites Ninety-nine percent of the 96 samples tested produced the expected result.
   b. Linearity/assay reportable range:

c. Traceability (controls, calibrators, or method):

d. Detection limit:
Table: Analytical Sensitivity

Influenza Strain	Type	Detection Limit $CEID_{50}$
A/Puerto Rico/8/34 (H1N1)	A	8.9×10^3
A/Fort Monmouth/1/47 (H1N1)	A	7.9×10^1
A/New Jersey/8/76 (H1N1)	A	8.9×10^1
A/Hong Kong/8/68 (H3N2)	A	2.8×10^1
A/Victoria/3/75 (H3N2)	A	8.9×10^2
A/Port Chalmers/1/73 (H3N2)	A	4.0×10^1
B/Lee/40	B	7.9×10^3
B/Allen/45	B	4
B/Maryland/1/59	B	6
B/GL/1739/54	B	8.9×10^1
B/Taiwan/2/62	B	3
B/Hong Kong/5/72	B	1.58×10^2

e. Analytical specificity:
Thirty-six microorganisms were evaluated with the Xpect™ Influenza A/B test. No cross-reactivity was observed for influenza A or influenza B.

f. Assay cut-off:

2. Comparison studies:

a. Method comparison with predicate device:

Clinical Accuracy:

Comparison studies were conducted at 3 sites. For all specimens evaluated, the overall sensitivity of the Xpect™ Influenza A/B test when compared to culture was 92.2% (71/77) for influenza A and 97.8% (45/46) for influenza B. The overall specificity was 100% for both influenza A (314/314) and influenza B (345/345).

Sample types

Nasal Wash/Aspirate (n=239)

Influenza A	Influenza B
92.5% Sensitivity (37/40)	100% Sensitivity; (36/36)
100% Specificity (199/199)	100% Specificity (203/203)

Throat Swabs (n=30)

Influenza A	Influenza B
100% Sensitivity (10/10)	100% Sensitivity; (4/4)
100% Specificity (20/20)	100% Specificity (26/26)

Nasal Swab (nasopharyngeal swab; nasal swab) (n=122)

Influenza A	Influenza B
88.9% Sensitivity (24/27)	83.3% Sensitivity; (5/6)
100% Specificity (95/95)	100% Specificity (116/116)

b. Matrix comparison:

3. Clinical studies:
   a. Clinical sensitivity:

   b. Clinical specificity:

   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

M. Conclusion:

The Performance characteristics reported here for the device indicate that it is comparable to the other such test kits currently in the market.